

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	Art Unit: 1645
ALBRECHTSEN, et al.)	Examiner:
Serial No.: 10/520,741)	Washington, D.C.
Filed: January 11, 2005)	March 30, 2006
For: USE OF COMPOUNDS CAPABLE)	Docket No.: ALBRECHTSEN=1
OF INHIBITING THE)	
PROTEOLYTIC PROCESSING...)	Confirmation No.: 2787

INFORMATION DISCLOSURE STATEMENT [IDS]

U.S. Patent and Trademark Office
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401 Dulany Street
Alexandria, VA 22314

S i r :

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed:

[] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application. See 37 CFR 1.97(b)(1) and (3).

[X] B. before the mailing date of a first office action on the merits. See 37 CFR 1.97(b).

[] C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary certification (box "i" below) or paid the necessary fee (box "ii" below). See 37 CFR 1.97(c)(2).

[] i. Counsel certifies that, upon information and

belief, each item of information listed herein was either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

- [] ii. Credit Card Payment Form, PTO-2038, authorizing payment for the fee set forth in 1.17(p), presently believed to be \$180, is attached.

[] D. after (A), (B) and (C) above, but before payment of the issue fee. Applicant petitions under 37 C.F.R. 1.97(d) for consideration of this IDS. A Credit Card Payment Form, PTO-2038, authorizing payment for the fee set forth in 1.17(p)(1), presently believed to be \$180 is attached. Counsel certifies that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

[] E. As a submission in accordance with the transitional procedure for limited examination after final rejection pursuant to 37 CFR §1.129(a). Pursuant to MPEP §706.07(g), page 700-66, col. 2 (August 2001), this IDS is treated as if filed with a period set forth in 37 CFR §1.97(b) and considered without the petition and petition fee required by 1.97(d).

[] F. As a submission with or after a request for continued examination under CFR §1.114, and before the mailing of a first office action on the RCE. See 37 CFR §1.97(b)(4).

2. In accordance with 37 C.F.R. 1.98, this IDS includes a

list (e.g., form PTO-1449) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document is attached, except as explained below.

[] While an IDS filed under §1.97 must contain a "list of all patents, publications or other information submitted for consideration by the Office", see §1.98(a) (1), the only requirement for the list is that it provide the information set forth in §1.98(b). There is no requirement that a form PTO-1449 be used (MPEP §609 merely says that use of this form is "encouraged"). Counsel has used a list provided to him by Applicants, and not transferred the information to a PTO-1449, to avoid the risk of any inadvertent error in transferring the information.

[X] A. Document AA is a U.S. Patents or U.S. Patent Publication, and hence a copy of this document has not been provided. See 37 CFR 1.98(a)(2)(ii).

[] B. Documents _____ are deemed substantially cumulative to documents _____, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.

[] C. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

[insert serial number/filing date]

Applicants identify these documents by attaching hereto copies of the form PTO-892s and PTO-1449s from the files of the prior applications or a fresh PTO-1449 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application. If copies of any of these documents cannot be found in the files of the prior applications, the Examiner is requested to so notify counsel before taking action in this case, so replacement copies can be submitted. While an IDS filed under §1.97 must contain a "list of all patents, publications or other information submitted for

consideration by the Office", see §1.98(a) (1), the only requirement for the list is that it provide the information set forth in §1.98(b). There is no requirement that a form PTO-1449 be used (MPEP §609 merely says that use of this form is "encouraged") and no prohibition on submitting a copy of a form PTO-1449 or form PTO-892 from a prior case. Indeed, the re-use of such forms is desirable as it avoids error in transferring the information, and evidences that the reference was considered in a prior application. A previously accepted PTO-1449, or an examiner-prepared PTO-892, necessarily complies with §1.98(b).

[X] 3. Document AM is not in the English language. In accordance with 1.98(a)(3), Applicants state:

[] documents _____ already contain an English language abstract, summary or claim set.

[] a publicly available abstract is attached to each of documents ____, and the source of each abstract is indicated thereon.

[] documents _____ are publicly available English language abstracts of foreign language patents. If the Examiner would like us to obtain a copy of the underlying document, with or without a translation, s/he should contact Counsel.

[] documents ____ are patents or published patent applications for which counterpart English language patents or patent applications exist, and are enclosed, as follows:

<u>Foreign Lang. Doc.#</u>	<u>English Lang. Doc.#</u>
[insert]	[insert]

[X] applicants have prepared an English abstract and a copy is attached.

[] A concise explanation of the relevance of documents _____ is found in the attached search report from the _____ Patent Office (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).

[] A concise explanation of the relevance of documents _

_____ appears in the present specification.
[] A concise explanation of the relevance of documents
_____ is set forth as follows:

[Insert concise explanation of relevance]

4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

5. If the month of publication of a nonpatent reference is not stated, it is because it is not apparent from review of the reference. If requested to do so by the Examiner, Applicants will attempt to locate and write to the publisher.

If the publication date of a cited document is set forth only as a publication year, and that year is prior to the year of filing or, if priority is claimed, year of priority of this application, then the particular month of publication is not in issue. Likewise if that publication year is after the year of filing of this application, the month of publication is not in issue.

If the date of publication of a nonpatent reference is stated, then, except as explained below, it is the nominal date stated in the reference, or in a larger document (journal or book) from which the reference was extracted. Applicants reserve the right to challenge this date by contacting the publisher to determine the actual shipment date, or by contacting recipients to determine the receipt dates.

6. Other information being provided for the examiner's consideration follows:

[insert other information]

7. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the

item and Applicant reserves the right to prove that the date of publication is in fact different.

8. The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this paper or credit any overpayment to Deposit Account No. 02-4035.

Respectfully submitted,

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FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT
LIST OF DOCUMENTS CITED BY APPLICANT
(Use several sheets if necessary)

ATTY DOCKET NO: ALBRECHTSEN=1

SERIAL NO: 10/520,741

APPLICANT: ALBRECHTSEN, et al.

FILING DATE: January 11, 2005

GROUP:

U.S. PATENT DOCUMENTS (include at least patentee, patent number and issue date)

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	PATENTEE	CLASS	SUB- CLASS	FILING DATE IF APPROP.
AA	9 9 9 9 2 2 2	9 November 1999	Jacobs et al.			

FOREIGN PATENT DOCUMENTS (include at least document number, publication date and country)

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES/NO
AB	9 9 4 7 9 7 1	23 September 1999	WIPO			N/A
AI	0 0 0 1 5 5 6	19 July 2001	WIPO			N/A
AD	1 1 4 1 2 0	1 March 2001	WIPO			N/A
AE	0 0 0 0 2 1	15 June 2000	WIPO			N/A
AF	5 1 01 1 5 5 9	15 March 2001	WIPO			N/A
AG	0 1 0 0 1 0 3	7 June 2001	WIPO			N/A
AI	0 0 1 0 0 1 0	10 September 1999	WIPO			N/A
AI	0 0 0 0 0 0 0	1 December 1999	EP			N/A
AJ	0 3 1 1 1 6 1	10 June 1993	WIPO			N/A
AK	0 4 1 0 7 3	21 July 1994	WIPO			N/A
AL	9 9 9 1 9 2 4	14 October 1999	WIPO			N/A
AM	0 0 0 0 0 0 0	20 June 1999	EP			N/A

OTHER DOCUMENTS (include author, title, name of publication, volume, pages & date of publication)

AN	Adams, R.H., et al. "The chemorepulsive activity of secreted semaphorins is regulated by furin-dependent proteolytic processing" The EMBO Journal, Vol. 16 No. 20 pp.6077-6086, 1997.
AO	Bassi, D.E., et al. "Furin inhibition results in absent or decreased invasiveness and tumorigenicity of human cancer cells" PNAS, August 28, 2001, Vol.98 No. 18, pp.10326-10331.
AP	Martin-Satue, Mireia et al. "Identification of semaphorin E gene expression in metastatic human lung adenocarcinoma cells by mRNA differential display" Journal of Surgical Oncology 1999; 72,18-23.
AQ	Christensen, C.R.L., et al. "Transcription of a novel mouse semaphorin gene, <i>M-semaH</i> , correlates with the metastatic ability of mouse tumor cell lines" Cancer Research 58, 1238-1244, March 15, 1998.
AR	Christensen, C.R.L., et al. "SEMA3E affects endothelial cell motility <i>in vitro</i> and increases lung colonisation by tumor cells <i>in vivo</i> " Clinical & Experimental metastasis, vol. 18, No. 2, 2000, p161.
AS	Mangasser-Stephan, K., et al. "Identification of Human Semaphorin E Gene Expression in Rheumatoid Synovial Cells by mRNA Differential Display" Biochemical and Biophysical Research Communications 234, 153-156 (1997)

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		FILING DATE: January 11, 2005	GROUP:
OTHER DOCUMENTS (include author, title, name of publication, volume, pages and date of publication)			
AT	Delaire, S., et al. "Biological Activity of Soluble CD100. II. Soluble CD100, Similarly to H-SemaIII, Inhibits Immune Cell Migration" The Journal of Immunology, 2001, 166: 4348-4354.		
AU	Jean, F., et al. "A protein-based therapeutic for human cytomegalovirus infection" PNAS March 14, 2000. Vol. 97, No. 6, pp. 2864-2869.		
AV	Nagahara, H., et al. "Transduction of full-length TAT fusion proteins into mammalian cells: TAT-p27 ^{Kip1} induces cell migration" Nature Medicine, Vol. 4, No. 12, Dec. 1998. Abstract, pp. 1149-1452		
AW	Rohm, B., et al. "The semaphoring 3A receptor may directly regulate the activity of small GTPases" FEBS Letters, 486 (2000) 68-72.		
AX	Tamagnone, L., Comoglio, P.M. "Signalling by semaphorin receptors: cell guidance and beyond" trends in Cell Biology (vol. 10) September 2000, 377-383.		
AY	Database Biosis Biosciences Information Service, Philadelphia, PA, US, March 2001, 2001-03, Williamson Magali et al. "Over expression of semaphorin 3E in prostate cancer"		
AZ	Agrawal, S., et al. "GEM 231, a second-generation antisense agent complementary to protein kinase A α subunit, potentiates antitumor activity of irinotecan in human colon, pancreas, prostate and lung cancer xenografts" Int. Jour. Of Oncology, 21: 65-72, 2002.		
BA	Arora, V., et al. "Bioavailability and efficacy of antisense morpholino oligomers targeted to c-myc and cytochrome P-450 3A2 following oral administration in rats" Jour. Of Pharmaceutical Science, Vol. 91, No. 4, April 2002, pp. 1009-1018.		
B€	Bassi, DE., et al. "The proprotein convertases furin and PACE4 play a significant role in tumor progression" Molecular Carcinogenesis, 28: 63-69, 2000.		
BC	Bassi, DE., et al. "Elevated furin expression in aggressive human head and neck tumors and tumor cell lines" Molecular Carcinogenesis, 31: 224-232, 2001.		
BD	Beaucage, SL., et al. "Deoxynucleoside phosphoramidites-A new class of key intermediates for deoxypolynucleotide synthesis" Tetrahedron Letters, Vol. 22, No. 20, pp.1859-1862, 1981.		
BE	Bird, RE., et al. "Single-chain antigen-binding proteins" Science, Vol. 242, 21 Oct. 1988, pp. 423-426.		
BC	Brambilla, E., et al. "Semaphorin SEMA3F localization in malignant human lung and cell lines" American Jour. Of Pathology, Vol. 106, No. 3, March 2000, pp. 939-950..		
BC	Castellani, V., et al. "Analysis of the L1-deficient mouse phenotype reveals cross-talk between Sema3A and L1 signalling pathways in axonal guidance" Neuron., Vol. 27, 237-249, August 2000.		
BH	Chen, H., et al "Neuropilin-2, a novel member of the neuropilin family, is a high affinity receptor for the semaphorins sema E and sema IV but not sema III" Neuron., Vol. 19, 547-559, September 1997.		
BI	Clackson, T., et al. "Making antibody fragments using phage display libraries" Nature, Vol. 352, 15 August 1991, pp. 624-628.		
BJ	Chothia, C., et al "Domain association in immunoglobulin molecules - the packing of variable domains" J. Mol. Biol. (1985) 186, 651-663.		
EXAMINER		DATE CONSIDERED	
EXAMINER: Initial if reference considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			

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	BK	Cunningham, BC., et al. "High-resolution epitope mapping of hGH-receptor interactions by alanine-scanning mutagenesis" Science, Vol. 244, 2 June 1989, pp. 1081-1085.	
	BL	Hall, KT., et al. "Human CD100, a novel leukocyte semaphorin that promotes B-cell aggregation and differentiation" Proc. Natl. Acad. Sci. USA., Vol. 93, pp. 11780-11785, October 1996, Immunology.	
	BM	Holliger, P., et al. "Diabodies": Small bivalent and bispecific antibody fragments" Proc. Natl. Acad. Sci., USA., Vol. 90, pp. 6444-6448, July 1993, Biophysics.	
	B●	Holmes, MA., et al. "Structural consequences of humanizing an antibody" The Jour. Of Immunology, 1997, 158: 2192-2201.	
	BO	Jones, PT., et al. "Replacing the complementarity-determining regions in a human antibody with those from a mouse" Nature, Vol. 321, 29 May 1986, pp. 522-525	
	BP	Kabanov, AV., et al. "A new class of antivirals: antisense oligonucleotides combined with a hydrophobic substituent effectively inhibit influenza virus reproduction and synthesis of virus-specific proteins in MDCK cells" FEBS Letters, Vol. 259, No. 2, 327-330, January 1990.	
	BQ	Köhler, G., Milstein, C. "Continuous cultures of fused cells secreting antibody of predefined specificity" Nature, Vol. 256, Aug. 7, 1975, 495-497.	
	B●	Kolodkin, AL., et al. "The semaphorin genes encode a family of transmembrane and secreted growth cone guidance molecules" Cell, Vol. 75, 1389-1399, Dec. 31, 1993.	
	BS	Letsinger, RL., et al. "Cholesteryl-conjugated oligonucleotides: Synthesis, properties, and activity as inhibitors of replication of human immunodeficiency virus in cell culture" Proc. Natl. Acad. Sci., USA. Vol. 86, pp.6553-6556., September 1989. Biochemistry.	
	BT	Lopez de Menezes, DE., Mayer, LD. "Pharmacokinetics of Bcl-2 antisense oligonucleotide (G3139) combined with doxorubicin in SCID mice bearing human breast cancer solid tumor xenografts" Cancer Chemotherapy and Pharmacology, 2001.	
	BU	Manoharan et al., "Chemical modifications to improve uptake and bioavailability of antisense oligonucleotides" 1992, Ann NY Acad Sci 660:306-9	
	BV	Manoharan et al., "Introduction of a lipophilic thioether tether in the minor groove of nucleic acids for antisense applications" 1993, Bioorg Med Chem Let 3:2765-70	
	BW	Manoharan et al., "Cholic acid-oligonucleotide conjugates for antisense applications" 1994, Bioorg Med Chem Let 4:1053-60	
	BX	Manoharan et al., "Oligonucleotide conjugates: Alteration of the pharmacokinetic properties of antisense agents" 1995, Nucleosides & Nucleotides 14:969-973	
	BY	Manoharan et al., "Lipidic nucleic acids" 1995, Tetrahedron Lett 36:3651-54	
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	BZ	Marks et al., "By-passing immunization" 1991, J Mol Biol 222: 581-597	
	CA	Matthes et al., "Simultaneous rapid chemical synthesis of over one hundred oligonucleotide sona a microscale" 1984, EMBO J 3:801-805	
	CB	Mercapide et al., "Inhibition of furin-mediated processing results in suppression of astrocytoma cell growth and invasiveness" 2002, Clin. Cancer Res. 8:1740-6	
	CC	Miao et al., "Neuropilin-1 expression by tumor cells promotes tumor angiogenesis and proression" 2000, FASEB J 14:2532-9	
	CD	Miller. "Baculoviruses as gene expression vectors" 1988, Ann Rev Microbiol 42:177-99	
	CF	Mishra et al., "Improved leishmanicidal effect of phosphorotioate antisense oligonucleotides by LDL-mediated delivery" 1995, Biochim Biophys Acta 1264:229-237	
	CF	Miyazaki et al., "Developmental localization of semaphorin H messenger RNA acting as a collapsing factor on sensory axons in the mouse brain" 1999, Neuroscience 93:401-8	
	CF	Morrison et al., "Chimeric human antibody molecules: Mouse antigen-binding domains with human constant region domains" 1984, Proc Natl Acad Sci 81, 6851-6855	
	CH	Needleman and Wunsch, "A general method applicable to the search for similarities in the amino acid sequence of two proteins" 1970, J. Mol. Biol. 48:443-453	
	CF	Novotny and Haber, "Structural invariants of antigen binding: Comparison of immunoglobulin V _L - V _H and V _L - V _L domain dimers" Proc. Natl. Acad. Sci. USA 82, 4592-4596 (1985)	
	CF	Oberhauser et al., "Effective incorporation of 2'-O-methyl-oligoribonucleotides into liposomes and enhanced cell association through modification with thiocholesterol" 1992, Nucl Acids Res 20:533-8	
	CK	Pack, et al., "Improved bivalent miniantibodies, with identical avidity as whole antibodies, produced by high cell density fermentation of <i>Escherichia coli</i> " Nov. 1993, BioTechnology 11:1271-77	
	CF	Pozas et al., "Age-dependant effects of secreted semaphorins 3A, 3F, and 3E on developing hippocampal axons; <i>In vitro</i> effects and phenotype of semaphoring 3A (-/-) mice" 2001, Mol Cell Neurosci 18:26-43	
	CM	Presta., "Antibody engineering" 1992, Curr Op Struct Biol 2:593-596	
	CN	Reichmann et al., "Reshaping human antibodies for therapy" March 1988, Nature 332, 323-327	
	CO	Saiki et al., "Primer-directed enzymatic amplification of DNA with a thermostable DNA polymerase" Jan 1988, Science 239:487-491	
	CP	Saison-Behmooaras et al., "Short modified antisense oligonucleotides directed against Ha-ras point mutation induce selective cleavage of the mRNA and inhibit T24 cells proliferation" 1991, EMBO J 10:1111-8	
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CQ	Sakai et al., "Mouse semaphorin H induces PC12 cell neurite outgrowth activating ras-mitogen-activated protein kinase signaling pathway via Ca ²⁺ influx" Oct. 1999, J Biol Chem 274:29666-71		
CQ	Sekido et al., "Human semaphorins A(V) and IV reside in the 3p21.3 small cell lung cancer deletion region and demonstrate distinct expression patterns" April 1996, Proc Natl Acad Sci U S A 93:4120-5		
CS	Shea et al., "Synthesis, hybridization properties and antiviral activity of lipid-oligodeoxynucleotide conjugates" June 1990, Nucl Acids Res 18: 3777-83		
CT	Svinarchuk et al., "Inhibition of HIV proliferation in MT-4 cells by antisense oligonucleotide conjugated to lipophilic groups" 1993, Biochimie 75:49-54		
CU	Tamagnone et al., "Plexins are a large family of receptors for transmembrane, secreted, and GPI-anchored semaphorins in vertebrates" Oct. 1999, Cell 99:71-80		
CV	Tavtitan et al., "Characterization of a synthetic anionic vector for oligonucleotide delivery using <i>in vivo</i> whole body dynamic imaging" April 2002, Pharm Res 19:367-76		
CW	Tomizawa et al., "Inhibition of lung cancer cell growth and induction of apoptosis after reexpression of 3p21.3 candidate tumor suppressor gene SEMA3B" Nov. 2001, Proc Natl Acad Sci U S A 98:13954-9		
CX	Trusolino and Comoglio, "Scatter-factor and semaphorin receptors: cell signaling for invasive growth" April 2002, Nature Rev Cancer 2:289-300		
CY	Vaswani, et al., "Humanized antibodies as potential therapeutic drugs" Aug. 1998, Annals Allergy, Asthma & Immunol 81:105-115		
CZ	Williamson et al., "Over expression of semaphorin 3E in prostate cancer" March 2001, Proceedings of the AACR, Vol. 42, Abs		
DA	Xiang et al., "Isolation of the human semaphorin III/F gene (SEMA3F) at chromosome 3p21, a region deleted in lung cancer" 1996, Genomics 32:39-48		
DB	Yamada et al. "Identification of semaphorin E as a non-MDR drug resistance gene of human cancers" Dec. 1997, Proc Natl Acad Sci U S A 94:14713-8		
DC	Ford CF, et al., "Fusion tails for the recovery and purification of recombinant proteins" (review) 1991, in Protein Expression and Purification 2:95-107		
DD	Crooke et al. "Pharmacokinetic Properties of several novel oligonucleotide analogs in mice" J. Pharmacol Exp Ther. 1996, 227: 923-937		
EXAMINER /Kimberly Chong/		DATE CONSIDERED 08/03/2008	
EXAMINER: Initial if reference considered. Draw line through citation if not in conformance <u>and</u> not considered. Include copy of this form with next communication to applicant.			